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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,579	09/09/1999	STEVE DE KECZER	IR98-7410	2931

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DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

file COPY

Office Action Summary

Application No.
09/393,579

Applicant(s)
De Keczer et al.

Examiner
Bennett Celsa

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 23, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 and 47-56 is/are pending in the application.
- 4a) Of the above, claim(s) 2-13, 17, 18, 20, 31, 34-36, 45, and 47-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 14-16, 19, 21-30, 32, 33, and 37-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

Applicant's amendment dated 6/23/03 in paper no. 18-19 is acknowledged.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 1-45 and 47-56 are currently pending.

Claims 2-13, 17-18, 20, 31, 34-36, 45 and 47-56 are withdrawn from further consideration.

Claims 1, 14-16, 19, 21-30, 32, 33 and 37-44 are under consideration.

Election/Restriction

2. Applicant's election without traverse of Group III (claims 14-16, 19-30, 32-44 and 46) in Paper No. 5 is again acknowledged.

3. Applicant's further election of species, in Paper No.5 of :

- a. *α -bromoacetylbenzoic acid (BABA) as the "protected alkylating agent".*
- b. phosphine as the "disulfide reducing agent";
- c. alkaline phosphatase as the "activating agent capable of deprotecting to the protected alkylating agent"; and
- d. an antibody as the "reagent capable of specifically binding to modified homocysteine", is acknowledged, which reads on claims 1, 14-16, 19, 21-30, 32, 33, 37-44 and 46. Because

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applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)) .

It is noted that the sake of expediency and compact prosecution, claim 1 was included in the elected invention since claim 14 is dependent thereon.

4. This application contains nonelected claims. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawn Objection (s) and/or Rejection(s)

Applicant's amendment and arguments have overcome the new matter rejection of claims 1, 14-16, 19, 21-30, 32, 33 and 37-44 in item 3 of the prior office action.

Applicant's amendment and arguments have overcome the indefinite rejection of the claims regarding items A and B in the prior office action.

Applicant's amendment and arguments have overcome the indefinite rejection of the claims regarding item C in the prior office action relating to indefiniteness regarding the "portion of the alkylating agent being derivatized with a protecting group".

The indefinite rejection of the claims presented in items D-F of the prior office action are hereby withdrawn in view of applicant's amendment and arguments relating thereto

Applicant's amendment and arguments were considered and deemed persuasive for overcoming the rejection of claims 1 and 14 under 35 U.S.C. 102(b,e) as being anticipated or in the alternative as prima facie obvious over Metzger et al. US Pat. No. 5,700,910 (12/97)

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Applicant's amendment and arguments were considered and deemed persuasive for overcoming the rejection of claims 1, 14-16, 19, 21-30, 32, 33 and 37-44 under 35 U.S.C. 102(b) as being anticipated or in the alternative as being obvious over Van Atta et al. US Pat. No. 5,478,729 (12/95) alone or in view of the present specification to demonstrate inherency.

Applicant's amendment and arguments were considered and deemed persuasive for overcoming the rejection of claims 1, 14-16, 19, 21-30, 32, 33 and 37-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 5,478,729 alone or, if necessary, in view of the present specification to demonstrate inherency.

Outstanding Objection (s) and/or Rejection (s)

Claim Rejections - 35 USC § 112

5. Claims 1, 14-16, 19, 21-30, 32, 33 and 37-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

C. In claims 1, 19, 32 and 44 (and claims dependent thereon), use of the term "said alkylating agent having its haloketone or alpha haloaldehyde functional group derivatized with a protected functional group" is indefinite as to the metes and bounds of "functional group derivations" within the scope of the claim; and the resulting final structure of the derivatized functional groups of the alkylating agent.

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Discussion

Applicant's amendment and arguments were considered and deemed persuasive with regard to items A, B and D-F in the prior office action but partially persuasive with regard to item C.

With regard to the remaining portion of item C, Applicant's amendment and arguments regarding the metes and bounds of "functional group derivatiions" and resulting final structure has not been addressed by either applicant's amendment or arguments, and as such is retained.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative as prima facie obvious over CAPLUS AN 1991:631804 to Schepin et al. Zhurnal Organicheskoi Khimii (1990) Vol. 26(11) pages 2394-7 (and RN 13654-49-4 and RN 136454-32-5) alone or if necessary further in view of the specification to demonstrate inherency.

Amended claim 1 can be interpreted as a **product-by -process** claim drawn to "an alkylating agent" made by reacting an "haloketone or alphahaloaldehyde" containing a functional group (e.g. a carbonyl) with a "protected functional group" (e.g. derivatized); the resulting protected functional group (e.g. a carbonyl protecting group) resulting in the claimed degree of activity when exposed to an enzyme and a nucleophile or sulfhydryl group.

The Schepin Abstract discloses compounds (e.g. see RN 13654-49-4 and RN 136454-32-5) which are "Protected haloketone" alkylating compounds within the scope of the present invention as described in the present specification (e.g. pages 1-3) and formula (e.g. see

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specification page 9, lines 20-25); wherein the reference compounds are derivatives of “alphahaloketones” (e.g. alkylating agents) have an acyl (e.g. ester) protecting groups. The reference compounds are thus “protected haloketone” alkylating compounds within the presently claimed invention in light of applicant’s own specification teaching and thus must satisfy the new limitations regarding derivation and reactivity as summarized in the above paragraph.

Discussion

Applicant’s arguments directed to the above rejection were considered but deemed nonpersuasive for the following reasons. It is noted that the above rejection was modified in response to applicant’s amendment (e.g. “physiological “ supported on pages 1-3)

Applicant argues that Schepin does not disclose an alkylating agent having a carbonyl of a haloketone or alpha haloaldehyde functional group substituted with a protected functional group.

This argument was considered but deemed nonpersuasive.

The Schepin compounds (e.g. see RN 13654-49-4 and RN 136454-32-5) are clearly encompassed within the scope of the present invention as described in the present specification since it represents a derivatized alkylating agent (e.g. alphahaloketone) having an acyl protective group; and additionally the reference compounds are within the scope of the specification formula (e.g. see specification page 9, lines 20-25) which describes “protected haloketones”.

Accordingly, this rejection is hereby maintained.

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New Objection (s) and/or Rejection (s)

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstract No. 57:7553i (1957) to Jaques et al., "Toxicology and Pharmacology of a systemic phosphoric acid ester insecticide phosphamidon" and compound corresponding to RN 89490-23-3 and the specification (e.g. pages 1-4) for evidence of inherency.

Jaques et al. disclose a phosphate protected (e.g. enol phosphate via carbonyl) alpha halo (e.g. chloro) ketone. The unprotected reference alpha-haloketone is inherently an alkylating agent within the scope of the presently claimed invention (e.g. see specification page 1). The reference phosphate group would protect the "carbonyl" of the underlying alkylating agent from "nucleophilic or sulfhydryl" reaction under "physiological conditions"; and the phosphate would be cleavable (e.g. deprotected) by an enzyme (e.g. phosphatase) within the scope of the presently claimed invention (e.g. see specification page); thus rendering the resultant deprotected compound reactive to nucleophilic/sulfhydryl physiological conditions.

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Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

September 4, 2003

BENNETT CELSA
PRIMARY EXAMINER

